AWARD NUMBER: W81XWH-14-1-0299

TITLE: Conversion of Clinical Data from the NABISH I & II into FITBIR

PRINCIPAL INVESTIGATOR: Emmy R. Miller, PhD, RN

CONTRACTING ORGANIZATION: Virginia Commonwealth University

Richmond, VA 23284

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Introduction: This report summarizes the work done by a very small team (PI – Miller, Co-Is – McCauley, Wilde, Fourwinds) a 12-month project to prepare a related group of legacy data sets for addition to the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System. The first quarter of the funding period (9/30/2014 – 12/31/2015) was occupied with completing the necessary administrative/financial paperwork for the Baylor College of Medicine (BCM) Office of Sponsored Projects (OSP) and with obtaining IRB and HRPO approvals. During this delay, we moved forward with some preliminary project planning but were explicitly prohibited by the Baylor IRB from starting formal work on the project until HRPO approval was obtained. We were notified by HRPO that our project, as a technical data re-formatting project, did not require their approval as human subjects research in late December. During the second quarter (1/31/2015-3/31/2015), we were able to accomplish several important objectives, including project start-up, preparing the legacy data sets for analysis, creating/reconciling variable lists from the three data sets, and preparing a working file of relevant Common Data Elements (CDEs) and Unique Data Elements (UDEs) from the current FITBIR Data Dictionary. In the third quarter (4/1/2015 – 6/30/2015), we moved from analysis to synthesis, with over 300 NABISH variables mapped to CDEs (149) and existing UDEs (65), or to the 117 new UDEs we have identified and defined. We also requested and obtained Pseudo GUIDs, the FITBIR-required Global Unique Identifier, for 465 subjects in the three data sets. In the fourth quarter (7/1/2015 - 9/29/2015), the translation of the mapped variables into the required FITBIR Forms Structures was initiated. It was also clear that the work of this project could not be completed within the award time period, so Dr. Miller notified the BCM Office of Sponsored Projects to request an Extension without Funds (EWOF), which was subsequently approved. During this last quarter of the funding period, Dr. Miller accepted a position at Virginia Commonwealth University (VCU), ending her faculty appointment at Baylor and relocating there in mid-September to assume a new position. Notification to both BCM and VCU regarding the transfer of this award was done in early August, but that process has taken considerably longer than anticipated. All work and distribution of funds from BCM for this project ended on August 31, 2015; however, at this point (9/6/2016) the transfer has been processed, and we are preparing to resume work on this project in the next few weeks.

Keywords and Acronyms:

Common Data Elements (CDEs)

FITBIR – the Federal Interagency Traumatic Brain Injury Research Informatics System

Form Structures

Hypothermia

NABISH – the National Acute Brain Injury Study: Hypothermia I, II, and II Revised (IIR)

Traumatic Brain Injury (TBI)

Unique Data Elements (UDEs)

Variable

Variable-mapping

Accomplishments: The Specific Aims of this project were to: 1) prepare the data sets from NABISH I, II and IIR for upload into FITBIR, 2) upload the data to FITBIR using their required validation and upload procedures, and 3) verify that these data were uploaded correctly. This has been a primarily technical project to add value to FITBIR through the provision of detailed, carefully monitored, and similarly structured data sets that included 465 subjects with severe traumatic brain injury. In addition, the standard clinical management for all three trials was consistent in that it conformed to the Guidelines for Management of Severe Traumatic Brain Injury¹⁻³, making these data a robust and valuable addition.

The work plan to accomplish these objectives was detailed and provided essential guidance as we prepared for (first quarter) and then began project implementation (second quarter). Managing project scope was a significant issue, in that the NABISH data sets contained over 1,000 discrete variables, and we knew it simply would not be possible to prepare all of these variables for submission to FITBIR, even if there were CDEs to which they could be mapped.

<u>Accomplishment 1</u>: We identified several strategies for selecting and organizing both the NABISH variables and the FITBIR data elements, both CDEs and existing UDEs, including:

- 1. Limiting the FITBIR domains where we will search for data elements to map to the NABISH variables. We selected the domains for General (i.e. all subjects) and TBI; however as of November 2014, this included almost 3,500 data elements in the Basic, Core, or Supplemental groups.
- 2. Focusing on three major variable types in the NABISH data sets:
 - a. Variables necessary to describe the subjects and the study protocol correctly and fully
 - b. Variables listed as Core/Basic for Severe TBI
 - c. Variables that may be Unique or even absent from FITBIR that:
 - i. Are necessary to fully describe variables submitted in 2.a-b. above
 - ii. Offer value for severe TBI investigators, such as variables related to body temperature.

After setting boundaries for this somewhat overwhelming project, the next step was to review, analyze, and categorize the NABISH variables and to make preliminary selections of these. With this list in hand, we turned to the FITBIR Data Dictionary to search for CDEs or existing UDEs that <u>might</u> correspond to the NABISH variables. Due to the evolving nature of FITBIR, specifically the limited nature of tools it provided and the lack of structure and consistency in the data elements themselves, this process was frustrating and difficult, and often required considerable re-work.

<u>Accomplishment 2</u>: We created detailed, annotated lists of NABISH variables for use across all three data sets. This work included:

- 1. Selecting and retaining only enrolled subjects, as the data sets for the screened/excluded subjects was both limited and incomplete in some cases to make it a valuable addition.
- 2. Matching variable names, definitions, and data values across all three data sets.
- 3. Verifying that calculated variables (e.g. min/max daily value, scores such as TIL) were calculated consistently in all three data sets.

The result of this work was a set of Master Data Tables, with variables and subjects summarized in Table 1 below.

Table 1: NABISH Data Sets							
N-I N-II N-IIR							
# tables	40	22	21				
# variables	903	720	1096				
# subjects	375	22	97				

Our intention was to map as many NABISH variables to CDEs as possible, because using the CDEs will make the FITBIR database easier for future investigators to search effectively. We planned to add UDEs only if they truly represent something unique and different from CDEs or existing UDEs. However, these efforts have been hindered by several intrinsic characteristics of the current FITBIR database, including duplicate/redundant CDEs and existing UDEs, limited options for Permissible Variables (PVs) that preclude the use of CDEs, and lack of defined data structures such as numbering/coding schemes for CDEs/UDEs, incomplete/truncated PV lists, and inconsistent assignment of data elements to Domains/subdomains.

Several conference calls were held with the FITBIR Operations Team during this period, in order to identify strategies to move forward with our work.

Mapping NABISH variables to the available FITBIR data elements was a considerable challenge. Finding relevant data elements in FITBIR was challenging, as shown in Table 2 below, where searches for "intracranial pressure" and "ICP" produced very different results.

Table 2: Query Results with Different/Related Search Criteria

query title "intracranial pressure"

external IDNINDS	element type	lement type title				
C01566	Common Data Element	Intracranial pressure monitoring start date and time				
C01567	Common Data Element	Intracranial pressure monitoring stopped reason				
C01568	Common Data Element	Intracranial pressure monitoring stop date and time				
C01569	Common Data Element	Intracranial pressure monitoring problem type				
C01570	Common Data Element	Intracranial pressure <u>catheter</u> revised indicator				
C01571	Common Data Element	Intracranial pressure <u>catheter</u> anatomic site				
C01572	Common Data Element	Intracranial pressure device type				
C01573	Common Data Element	Intracranial pressure measurement				
C01574	Common Data Element	Intracranial pressure maximum daily measurement				
C01575	Common Data Element	Intracranial pressure mean daily <i>measurement</i>				
C01576	Common Data Element	Intracranial pressure episode greater 20 mmHg longer 5 minutes number				
C01577	Common Data Element	Intracranial pressure episode greater 20 mmHg number				
C14026	Common Data Element	Intracranial pressure (ICP) result				
C14027	Common Data Element	Intracranial pressure (ICP) other measurement text				
C18725	Common Data Element	Intracranial pressure <u>catheter</u> other text				
C18726	Common Data Element	Intracranial pressure device other text				
C18727	Common Data Element	Intracranial pressure monitoring problem other text				
	Unique Data Element	Intracranial pressure device type TRACK TBI				
	Unique Data Element	Intracranial pressure device type TRACK TBI other text				

query title "ICP"

external IDNINDS	element type	title
C14026	Common Data Element	Intracranial pressure (ICP) result
C14027	Common Data Element	Intracranial pressure (ICP) other measurement text
	Unique Data Element	ICP Catheter indicator
	Unique Data Element	ICP Monitor placed at non-Study hospital Indicator
	Unique Data Element	ICP Monitor Placement Indicator
	Unique Data Element	ICP monitor placement indicator
	Unique Data Element	New cranial CT completed within 12 hours of when ICP became sustained above 25 mm Hg for 60 minutes indicator
	Unique Data Element	Reason why no ICP monitor was ever used
	Unique Data Element	Reason why no ICP monitor was ever used other text

Once data elements that "seem like" the variable are identified, the next dilemma was to see if the FITBIR Permissible Values (PVs) were consistent with the NABISH data values. An example of situations where the PVs "don't quite fit" is shown in Table 3 below. Note the CDE for Discharge Destination from the ED has 8 PVs designed to cover a wide range of clinical situations; however, the NABISH data values are specific for severe TBI clinical care i.e. some patients leave the ED to go immediately to the operating room (OR) or for a head CT scan prior to actually being admitted to the ICU. And while they ultimately do get admitted to the ICU, identifying those who do go elsewhere prior to the ICU is valuable. Since CDE 04811 has no option for these two data values, the question becomes: Do we code all three NABISH data values to "Admission to hospital – ICU" or create a new UDE that reflects our data values? In a new study, planning for their data to go into FITBIR, it would be possible to structure data entry procedures to capture this

emergency OR visit or CT scan another way. But, with a legacy data set, this seemingly simple datum is fraught with questions.

Table 3: CDE and Variable Map but PV and Data Values Do Not

CDE C04811	C04811 Permissible Values	NABISH Data Values
ED discharge destination type	Admission to hospital - ICU	ICU
	(no option)	Operating Room
	(no option)	Radiology – CT Scan
	Admission to hospital - intermediate/high care unit	
	Admission to hospital - other (e.g., observation unit)	
	Admission to hospital - ward;	
	Discharge to home	
	Discharge to nursing home	
	Discharge to other hospital	
	N/A - patient died	

<u>Accomplishment 3</u>: Despite the challenges of FITBIR's evolving status, we identified a working list of CDEs and exiting UDEs from the General and TBI domains to begin our work. The initial list contained over 2,000 potential data elements.

If a suitable CDE/existing UDE was available that "fit" the meaning and clinical intent of the NABISH variable, then both the variable/data element name and the NABISH data values/Permissible Values (PVs) were mapped. This process ultimately determines which CDE/existing UDE to use or whether we would have to resort to a new UDE, because it was impossible to "shoe-horn" data values into the required PVs for some data elements that had similar names to NABISH variables. Sometime this was not possible, and a new UDE was required; in other situations, however, it was possible to perform data transformation procedures to "line up" the NABISH data values and the FITBIR data element PVs, so that an existing CDE or UDE could be used.

Accomplishment 4: We have developed a step-by-step analysis/documentation of the data transformation procedures required so that our existing variable/data values can be mapped to FITBIR data elements and permissible values (PVs). While not required for all variables, there have been quite a few of these. A cross-walk table, showing how the variables map across the NABISH studies to FITBIR data elements and PVs is provided in Table 4. This is a crucial step that we have included in our mapping process.

Table 4: Cross-walk Table for NABISH Tables and CDE C04809

NI:	N-II	N-IIR	CDE:C04809	
Variable:	Variable:	Variable:	Hospital Discharge	
Hospital Disposition	Disposition	Disposition	Destination type	
Death	Death	Death	Not applicable – patient died	
Nursing Home	Extended care facility/nursing home	Extended care facility/nursing home	Discharge to nursing home	
Discharged Home	Home	Home	Discharge to home/private residence	
	Inpatient Hospital	Inpatient Hospital	Discharge to other hospital	
	Long-term acute care facility Long-term acute care f		Other, specify	
Rehab	Rehabilitation facility	Rehabilitation facility	Discharge to rehabilitation unit	

These detailed lists and data transformation procedures, represented in Accomplishments 2-4, provided the foundation for our next accomplishment. As we struggled with the challenges of sorting, compiling, and mapping, Dr. Miller attended the FITBIR Stakeholders Meeting, April 21, 2015, during which she was able

to discuss issues and challenges with other FITBIR investigators as well as members of the FITBIR Operations Team.

<u>Accomplishment 5</u>: Over 300 NABISH variables are now mapped to CDEs and existing UDEs, or to the new UDEs we have identified/defined, including:

- 1. **149** CDEs have been mapped to NABISH variables, with many CDEs used for more than one variable
- 2. **65 existing UDEs** have been used when CDEs were not available, either in the clinical content area or because the PVs for the CDEs were not usable
- 3. 117 new UDEs have been identified and defined for submission, and it is likely that more may be required. Fifty-five have been entered on our FITBIR Data Element Import Template at this point.
 - a. Despite our commitment to use CDEs whenever possible, there are simply too many gaps in the acute care content areas covered by CDEs.
 - b. When CDEs might fit, PVs often do not include all needed data values, nor is there a selection of "Other, specify" to provide some flexibility.

A summary of the mapping work is provided below in Table 5.

Table 5. Variable-to-Data Element Wrapping to date												
NABISH I (n=368)				NABISH II (n=22)			NABISH IIR (n=109)					
Data Category	# variables	# Map - CDE	# Map - Ex UDE	# Map - New UDE	# variables	# Map - CDE	# Map - Ex UDE	# Map - New UDE	# variables	# Map - CDE	# Map - Ex UDE	# Map - New UDE
Protocol Data	99	40	8	43	85	40	8	36	87	40	8	38
Physiologic Data	208	36	11	27	71	36	2	1	84	39	2	1
Imaging Data	44	27	3	5	0				26	22	3	4
Treatment Data	68	7	5	7	61	7	6	9	75	8	7	9
Complication Data	164	12	19	15	31	15	20	17	38	15	20	19
Outcome Data	77	10	8	7	140	15	12	10	170	20	16	14
Total	660	132	54	104	388	113	48	73	480	144	56	85

Table 5: Variable-to-Data Element Mapping to date

While it may initially appear that only a small percentage of variables have been mapped, this is not the case. For example, for the N-I data set, a total of 290 variables have been mapped to either a CDE, an existing UDE, or a new UDE (44%); however, for N-IIR this percentage appears considerably higher at 59% (285 of 480 variables) because the data set had been streamlined by the time of this project.

In addition, these percentages of mapped variables may seem low for two reasons. First, many of the CDEs/UDEs were mapped to more than NABISH variable i.e. CDE C06246 Medical History Condition is used 14 times, where 11 had PV = Other, Specify, which then required CDE C18793 Medical History Condition Other. Next, many of the unmapped variables represent either redundant data collected or variables that were intended for local use by the study sites, i.e. monitoring study center performance and protocol compliance. Since these would have limited, if any utility for the FITBIR data set, they were not mapped.

In the last part of the fourth quarter, before work was suspended due to Dr. Miller's relocation, we had begun the process of setting up the FITBIR-required Form Structures. These Form Structure are the specifically constructed data tables that will be used to input the data into the FITBIR database. As the end of the work period, only a few of these had been set up and none had been reviewed by FITBIR or tested for upload performance.

In summary, this project has accomplished a substantial portion of the work of our first specific aim – to prepare the data sets from NABISH I, II and IIR for upload into FITBIR and to map NABISH variables to FITBIR data elements. Furthermore, this aim represented the major portion of the project's work, and it is the foundation to accomplish the remaining specific aims and complete the project. The project was halted, due to Dr. Miller's relocation, with four months remaining in the funding period/requested EWOF, which was the time allocated on the project work plan for the completion of these last two aims.

Since this project is not yet completed, we have no accomplishments to report regarding dissemination of the results. We do, however, plan to publish/present the valuable methods and procedures that have been developed from this project. In particular, there are lessons learned from our work that could provide useful direction for data planning for future trials, as well as for organizing data collection procedures and analysis.

Impact: As yet unknown, since the project is not completed.

Changes/Problems: FITBIR is a relatively new resource for data management and research, and as with any new system, there are issues. Problems that we have encountered during the project have included:

- 1. New data elements are being added and existing data elements are being revised every month. When we prepared the original application in September 2013, FITBIR had 938 published data elements, 340 CDEs and 598 UDEs. For the work reported here, we "froze" the FITBIR Data Dictionary in April 2015, which included 12,533 data elements, 8,944 CDEs and 3,589 UDEs.
- 2. Duplicate CDEs and CDEs/UDEs are a baffling problem for many categories of data for which there are NABISH variables. There are multiple CDEs for the same thing, and there are UDEs that are similar or even exact matches in some cases to existing CDEs. (See Table 2, p. 6 for an example)
 - a. Naming conventions for data elements are inconsistent, so searching the FITBIR data elements by text string produces inconsistent and incomplete results, as shown in Table 2.
 - b. While CDEs have an assigned NINDS ID#, there is no numbering/coding scheme provided for UDEs. Thus, efforts to identify potentially useful existing UDEs are contingent on a text-string query.
- 3. Problems with "fit" of the CDEs with clinical variables, including:
 - a. Temporal representation of data (i.e. hourly, daily, on admission, etc) is either non-existent, requires multiple CDEs (i.e. one for the variable and one for the time frame), or is counterintuitive.
 - b. Important clinical areas have limited CDEs available, e.g. Mean Arterial Pressure, a key variable for critical care management and for calculation of cerebral perfusion pressure, exists only as a recently-added UDE.
 - c. Complications are hard to find in the available CDEs, yet represent a crucial aspect of TBI research. Of the 49 coded complications in the NABISH data set, only 11 had a corresponding CDE. Another five were located in the PVs for 2 additional CDEs, and 16 are similar to existing UDEs. At this point, only 32 (65%) can be mapped with existing data elements, so new UDEs for the remaining 17 will be created.
- 4. *Limited resources of the FITBIR Operations Team* presented continuous difficulties throughout the project, such as:
 - a. There was turnover among the team members. While this project was active, we were assigned three different team members as the Points-of-Contact (POC) for this project. Lack of transition planning or "'hand-off' procedures were clear in the repeated requests for previously-provided materials and clear lack of familiarity with our project. This was hard

- on our POC, because they were always at the start of the learning curve about the project, and it was incredibly frustrating for us in trying to get answers to questions or other support.
- b. There was not data analyst on the Team with clinical knowledge to bridge the gap between data issues and clinical questions. Questions raised about *which* CDE among several that appear similar go unanswered, not because the Team doesn't want to help it is just outside their expertise, which is primarily technical. And there are simply no other resources to go to for this type of help, other than the FITBIR Team.
- c. The Team appears to have a narrowly circumscribed set of duties and responsibilities, as evidenced by:
 - i. Focus on supporting documentation, rather than answering question about the current work or problems (see 4.b above).
 - ii. Creating UDEs. When questioned about how a CDE might be used/adapted for a specific situation, the recommendation has consistently been "why not create a UDE".
 - 1. This is particularly frustrating when a small change in the PVs would make an existing CDE usable; however, there appears to be no mechanism for this solution.
 - 2. This strategy also has long-term implications because the expanding plethora of UDEs that are similar to existing CDEs but necessary because PVs don't map is going to increase the difficulty and complexity of future efforts to conduct research out of this database.

The major change encountered during the project was Dr. Miller's relocation from Baylor to Virginia Commonwealth University. As new job offers can sometime happen quickly, there was a very short notification period for letting Baylor and CDMRP know about this move and to then start the process for transfer of the award. The result was that Baylor shut down funding on August 31, 2015 which was Dr. Miller's end date there. Subsequently, the award transfer process has moved forward, albeit very slowing, and we anticipate resuming work on this project in September 2016.

Products: None at this point. Research projects conducted through FITBIR using the NABISH data, either as a focus or in combination with other data sets, will be future projects.

Participants & Other Collaborating Organization: The individuals and organizations involved in this project have remained unchanged, with the exception of: 1) Dr. Miller's relocation to Virginia Commonwealth University, and 2) frequent turnover of the assigned FITBIR Operations Team Point of Contact (POC) for the project.

Table 6: Project Personnel

		3	
Personnel	Role	Institution	Percent Effort
Emmy R. Miller, PhD, RN Principal Investigator		Baylor College of Medicine (till 8/31/2015)	12
		Virginia Commonwealth University (current)	
Sierra Fourwinds	Co-Investigator/Technical Director	Silverwind Research, Inc.	40
Stephen R. McCauley, PhD	Co-Investigator	Baylor College of Medicine	3
Elisabeth A. Wilde, PhD	Co-Investigator	Baylor College of Medicine	3

Dr. Miller's primary responsibilities for this project have included overall direction of the project, participation in the analysis and deconstruction of the NABISH data sets, and clinical guidance for those project activities involving naming, defining, or other descriptive/clinical aspects of the technical data work. She has and will continue to work closely with Drs. McCauley and Wilde and Ms. Fourwinds to ensure accomplishment of these same procedures for the outcome variables. Dr. Miller will also ensure close collaboration among all project investigators and technical staff.

Ms. Fourwind's primary responsibilities for this project have included direction and supervision of all aspects of the data preparation, technical data mapping, UDE preparation, technical documentation of the project, and all activities related to the upload of NABISH data into FITBIR. Ms. Fourwinds has and will continue to ensure close collaboration among all project investigators and technical staff.

Dr. McCauley has assisted with analysis and deconstruction of the outcome data in the NABISH data sets, and clinical guidance for those project activities involving naming, definition, or other descriptive aspects of the technical data work. He has and will continue to work closely with the project investigators and technical staff.

Dr. Wilde has assisted with analysis and deconstruction of the outcome data and with the imaging data in the NABISH data sets, and clinical guidance for those project activities involving naming, definition, or other descriptive aspects of the technical data work. She has and will continue to work closely with the project investigators and technical staff.

Special Reporting Requirement: None

Appendix 1: Reference List

- 1. Bullock R, Chesnut RM, Clifton G et al. Guidelines for the management of severe head injury. Brain Trauma Foundation. Eur J Emerg Med 1996;3(2):109-127.
- 2. Bullock R, Chesnut R, Clifton G et al. Part I: Guidlines for the management of severe traumatic brain injury. J Neurotrauma 2000;17.
- 3. Bullock MR, Povlishock JT. Guidelines for the management of severe traumatic brain injury. Editor's Commentary. J Neurotrauma 2007;24 Suppl 1:2.

Conversion of Clinical Data from the NABISH I & II into FITBIR

W81XWH-14-1-0299

PI: Emmy R. Miller, PhD, RN

Org: Baylor College of Medicine Award Amount: \$115,263.00



Study Aims and Approach

Prepare data sets from NABISH I. II. and IIR for upload into FITBIR

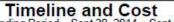
- Review and analyze the NABISH data sets
- Map NABISH variables to FITBIR CDEs where possible determine which remaining variables will be included as UDEs
- Format variables, prepare required documentation and descriptions
- Prepare subject identifiers needed for FITBIR to assign pseudo GUID for use during the upload process.

Upload data to FITBIR using their validation and upload procedures

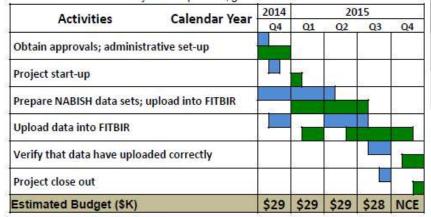
- Prepare data submission request, establish account, and create study per FITBIR data submission policy and procedures
- Prepare submission package(s) and submit to FITBIR; collaborate as needed to facilitate upload procedures.

Verify that data have uploaded correctly

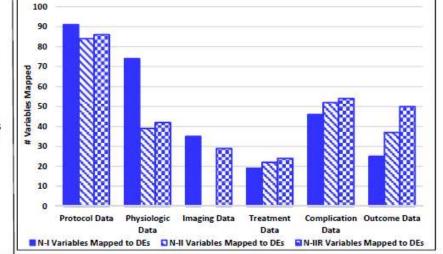
- Submit test gueries requesting data in all categories.
- Compare data sets obtained through these test queries to original study data: resolve discrepancies



Timeline and Cost
Original Funding Period – Sept 30, 2014 – Sept 29, 2015
Expected No-Cost Extension Year Funding – Sept 30, 2015 – Dec 31, 2015
Key: blue – planned, green – actual



Date: Oct 2015 - Annual Report



Goals/Milestones

CY14 - 4th Quarter Milestones - Approvals/Project Start-up

Approval Baylor IRB; HRPO designation as a technical project

CY15 - 1st Quarter Goals - Analysis/Preparation of Variables

Review NABISH data sets; map variables to FITBIR CDEs/UDEs CY15 - 2nd Quarter Goals - Data Preparation

Continue mapping/formatting NABISH variables

Prepare definitions/documentation of variables, tables

CY15 - 3rd Quarter Goals - Continue Data Preparation and Formatting

Finalize mapping/formatting

CY15 - 4th Quarter Goals (No-cost Extension) - Upload data to FITBIR, Verify upload and close out project

NOTE: Project shut down 8/31/2016

Prepare and test Form Structures

Submit test queries; verify accuracy of query results; resolve problems in collaboration with FITBIR

Budget Expenditure to date

Projected Expenditure: \$115,263.00

Actual Expenditure: \$76,842